IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA	)	
	)	**CRIMINAL ACTION FILE**
v.	)	
	)	**NO. 1:09-CR-0483-ODE/AJB**
RAJASHAKHER P. REDDY,	)	
	)	
Defendant.	)	

ORDER FOR SERVICE OF
REPORT AND RECOMMENDATION

Attached is the Report and Recommendation ("R&R") of the United States Magistrate Judge made in accordance with 28 U.S.C. § 636(b)(1) and N.D. Ga. CrR. 58.1(A)(3)(a), (b). A copy of the R&R and this order shall be served upon counsel for the parties.

Pursuant to 28 U.S.C. § 636(b)(1), each party may file written objections to the R&R within **fourteen (14)** days of service of this Order. Should objections be filed, they shall specify with particularity the alleged error(s) made (including reference by page number to the transcript if applicable) and shall be served upon the opposing party. *See United States v. Gaddy*, 894 F.2d 1307, 1315 (11th Cir. 1990). The party filing objections will be responsible for obtaining and filing the transcript of any evidentiary hearing for review by the District Court. If no objections are filed, the

R&R may be adopted as the opinion and order of the District Court and any appellate review of factual findings will be limited to a plain error review. *United States v. Slay*, 714 F.2d 1093 (11th Cir. 1983).

Pursuant to 18 U.S.C. § 3161(h)(1)(H), **the above-referenced fourteen (14) days allowed for filing objections is EXCLUDED from the computation of time under the Speedy Trial Act ("the Act"), whether or not objections are actually filed.** If objections to this R&R are filed, the Clerk is **DIRECTED** to **EXCLUDE** from the computation of time all time between the filing of the R&R and the submission of the R&R, along with any objections, responses and replies thereto, to the District Judge. 18 U.S.C. § 3161(h)(1)(D), (H); *Henderson v. United States*, 476 U.S. 321, 331 (1986); *United States v. Mers*, 701 F.2d 1321, 1337 (11th Cir. 1983). The Clerk is **DIRECTED** to submit the R&R with objections, if any, to the District Court after expiration of the above time period.

IT IS SO ORDERED and DIRECTED, this 24th day of February, 2011.

ALAN J. BAVERMAN
UNITED STATES MAGISTRATE JUDGE

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UNITED STATES MAGISTRATE JUDGE'S
FINAL REPORT AND RECOMMENDATION

Currently before the Court is the government's Motion to Preclude Expert Testimony. [Doc. 71]. For the reasons discussed below, the undersigned **RECOMMENDS** that the motion be **GRANTED**.

Introduction

A grand jury originally returned an indictment against the defendant on November 3, 2009, [Doc. 1], which was superseded on December 2, 2009, [Doc. 23]. The indictment was again superseded on July 13, 2010, in a 37-count second superseding indictment, charging the defendant with: (1) wire fraud in violation of 18 U.S.C. § 1343, (Counts 1 through 25), [Doc. 67 at 1-7]; (2) mail fraud in violation of 18 U.S.C. § 1341, (Counts 26 through 32), [*id.* at 7-9]; (3) health care fraud in

violation of 18 U.S.C. § 1347, (Counts 33 through 36), [*id.* at 10]; and (4) falsification of records in a federal investigation, in violation of 18 U.S.C. § 1519, (Count 37). [*id.* at 10-11].[1, 2]

On June 25, 2010, the defendant informed the government that he might call Dr. Benjamin Sacks as an expert witness. (*See* Def't Exh. 5 from *Daubert* Hrg). The defendant indicated that Dr. Sacks would testify about the results of his peer review concerning a series of radiographic images that the defendant had previously interpreted. (*See id.*). Specifically, the defendant represented that Dr. Sacks's would testify "that after reviewing [a] random selection of 1060 cases in which [a Radiology Practice Assistant] performed an initial evaluation of a report signed by Dr. Reddy, 'there were no misrepresentations or patient issues identified.' " (*Id.*).

On July 27, 2010, the government moved to preclude this expert testimony or, in the alternative, to have a hearing on the basis for the expert opinion. [Doc. 71]. The defendant opposed the motion on August 17, [Doc. 79], and the government filed a reply brief on September 8, [Doc. 80]. The undersigned held an evidentiary hearing

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[1] Counts 1 through 32 and 37also allege the defendant's liability under the aiding and abetting statute, 18 U.S.C. § 2.

[2] The indictment also contains an asset forfeiture provision.

concerning the government's motion on September 23, 2010. [Docs. 81, 82, hereinafter "T:__"]. The government filed its post-hearing brief on November 1, 2010. [Doc. 83]. The defendant filed a response on December 6, 2010, [Doc. 87], and the government filed a reply brief on January 6, 2011, [Doc. 89].

Indictment Allegations

The second superseding indictment alleges that Dr. Reddy, a board-certified radiologist, devised a scheme to defraud "by claiming to have performed health care services that he did not in fact perform" between mid-2006 through January 2008. [Doc. 67 ¶¶ 1, 2A]. The defendant owns and operates Reddy Solutions, Inc. ("RSI"), an Atlanta-based teleradiology[3] company that offers around-the-clock professional radiology services to hospitals, imaging centers and radiology groups. [*Id.* ¶¶ 2A, 2B]. The hospital or other facility performed the X-Ray, Magnetic Resonance Image, CT Scan or other test on-site and then electronically transmitted the films or images to RSI for Reddy or an RSI-contract radiologist to review, and to prepare and send back a final report. [*Id.* ¶ 2B, 2C]. The final report typically contained clinical findings related to the images obtained and the medical diagnosis. [*Id.* ¶ 2B]. Although the defendant

[3] Teleradiology allows for a patient, hospital, or other RSI client to exchange information electronically to allow a radiologist who is not on sight to review film. [*Id.* ¶ 2B].

operated RSI, he also served as a radiologist for RSI and submitted signed reports to client hospitals and other providers. [*Id.* ¶ 2C].

Besides radiologists, RSI employs radiological technicians known as "Radiology Practice Assistants" ("RPAs"), who are not physicians and could not render clinical findings or diagnoses. [*Id.* ¶ 2D]. The RPA assists the radiologist by performing a preliminary review of films and data and may memorialize such review in draft radiology reports, "but a physician must subsequently perform an independent review of the radiology films and data before accepting the findings and diagnosis in the draft report and signing it." [*Id.*].

In 2007, RSI obtained more than $5 million in revenue from contracts with facilities around the country. [*Id.* ¶ 2E]. RSI did not directly bill Medicare and private insurers; instead, RSI's contracts with its clients required the clients to bill Medicare and other insurers for the radiology tests and RSI-performed services, which often were referred to as the professional component of the test. [*Id.* ¶ 2F]. The clients then remitted to RSI either a flat monthly fee, a fee per individual read, or a combination of both, depending on the compensation arrangement between RSI and the client. [*Id.*]. The client typically billed Medicare by way of an electronic wire communication to a regional Medicare processing company. [*Id.*].

The second superseding indictment alleges that Reddy fraudulently signed and submitted radiology reports for "tens of thousands" of patients to the hospitals and other RSI clients where neither he nor any other RSI physician had reviewed and analyzed the film. [*Id.* ¶ 3]. The indictment alleges that this was done as follows:

> [] For certain reports that he prepared, the Defendant . . . had a practice of having certain RPAs review the films first and prepare a draft report. Under the appropriate standard of care and in order to perform a legitimate physician's service, the Defendant should have confirmed the accuracy of the report by independently reviewing the images and the data, editing the draft report as necessary, and submitting the final report under his electronic signature.
>
> [] However, as an example, on more that 40,000 occasions from May 2007 through January 2008, the Defendant signed and submitted radiology reports under his name in cases where neither he nor any other RSI physician ever reviewed the underlying films and data. In other words, the Defendant simply passed off the draft reports prepared by his RPAs as final radiology reports reviewed by a board-certified radiologist, without any physician review.
>
> [] As the Defendant knew, the hospital or other RSI client then submitted bills to Medicare and private insurance companies for these tests, including for the supposed professional services of a qualified radiologist that never in fact occurred.
>
> [] RSI received over $1.5 million during this time for these specific, fraudulent, reports, which were not actually reviewed by a physician.

[*Id.* ¶¶ 3B-3E].

Facts

A. Dr. Manju Morrissey

1. Qualifications

Dr. Morrissey is the defendant's older sister. T:11. She also is a board certified physician in internal medicine. T:12. She earned her medical degree at Louisiana State University ("LSU") in 1992, performed her fourth year rotation at Harvard University, and returned to LSU to complete her residency in internal medicine from 1992-1995. T:12; Def't Exh. 4. Following her residency, Dr. Morrissey practiced medicine for several years as follows: (1) she was an emergency room attending doctor in Rochester, New York, from 1995-1997; (2) she practiced in primary care for a year in South Florida from 1997-1998; and (3) she worked in primary care in Boston from 1998-2001. T:12-13; Def't Exh. 4. Dr. Morrissey stopped practicing to attend Harvard University for a Master's degree in public health, which she obtained in 2002. *See* T:12, 13; Def't Exh. 4. During this time, Dr. Morrissey also worked at Massachusetts Peer Review Organization as a physician reviewer in which she reviewed cases to determine quality of patient care. T:31-32; Def't Exh. 4.[4] After earning her master's

[4] Dr. Morrissey did not design statistics or sampling in her job as a peer reviewer. T:32.

degree, Dr. Morrissey was employed by a pharmaceutical company from 2002-2007 and a medical device company from 2007-2008. T:13-14; Def't Exh. 4. In these positions, Dr. Morrissey worked in drug safety and worked on clinical trials. T:13-14. Dr. Morrissey then moved to RSI to work as its chief administrative officer. T:14.

While at Harvard, Dr. Morrissey studied statistics for nine months. T:14. She also had exposure to statistics in medical school and in her post-masters degree work when she evaluated data from clinical trials for the pharmaceutical and drug device companies. T:30. Dr. Morrissey did not obtain a degree or professional certification in statistics, but she worked with statisticians, examined their statistical plans and reviewed statistical data. T:30.

2. Methodology

After Dr. Morrissey arrived at RSI, she created and implemented a peer review to examine the defendant's radiology reports. T:14. Specifically, the peer review examined the accuracy of RPA-assisted cases that Dr. Reddy reviewed between April or May 2007 and March 2008. T:15-16, 48.

To devise the peer review, Dr. Morrissey relied on guidelines for self-audits in the Federal Register[5] published by the Office of Inspector General ("OIG") at the Department of Health and Human Services ("HHS"). *See* T:17, 19.[6] This peer review was to use "a statistically valid sample of the claims that [could] be projected to the population of claims affected by the matter for the relevant period." *See* T:19; *see also* Def't Exh.1 at 58402. To obtain a statistically valid sample size for the peer review, Dr. Morrissey turned to the RAT-STATS program. T:21. The OIG strongly recommended using this program to create a random sample to perform the self-assessment. Def't Exh. 1 at 58403. For the RAT-STATS program to generate a statistically valid sample size, it requires a few factors: (1) confidence level, which is how confident one wants the results from the sample data to reflect the results of the

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[5] According to the federal register, the purpose of the self-assessment guidelines is "[t]o estimate the monetary impact of the disclosed matter." *See* Def't Exh. 1 at 58402. Also, the Federal Register provided that the provider should submit a plan describing the self-assessment to the OIG, which would then review the proposal and provide comments. Def't Exh. 1 at 58402. Dr. Morrissey did not submit her proposal to OIG because of the context of RSI's situation, which was under a federal investigation, she was comfortable with the plan and the results were available to the government. T:42-43.

[6] Dr. Morrissey had not been aware of this OIG protocol until she needed to do the peer review. T:38. As a result, she had not been familiar with the RAT-STATS program prior to the peer review. T1:38-39.

larger data; (2) precision, which is the margin of error; (3) the universe size, which is the population being studied; and (4) rate of occurrence, which if unknown is to be 50%. T:22-23. Once values are assigned to each element, the RAT-STATS program provides a sample size. T:23.

Dr. Morrissey used the RAT-STATS program to obtain the appropriate sample size for her peer review. T:23, 35 ("I had a simple question which was I just needed to know how many records needed to be reviewed. So, basically, my only question was sample size."). She did not consult with anyone about how to determine the sample because she was comfortable with it. T:32, 44. Also, Dr. Morrissey did not examine the other methods of determining a sample size - - variable sample size, attribute sample size,[7] and stratified variable sample size - - listed in the RAT-STATS user's guide because she knew for what she was looking. T:36, 37; *see also* Def't Exh. 2 at 5-1 - 5-33. She just went to the computer program, which guided her with its input values. T:37.

To determine the appropriate sample size for the peer review, Dr. Morrissey assigned the following values: (1) 90% for confidence level; (2) 10% for precision;

[7] An attribute sample size is used if an individual knows the total population while a variable sample size is used if the population is unknown. T:64-65.

(3) 91,000 for the universe size[8]; and (4) 50% for the rate of occurrence. *See* T:23-24. The RAT-STATS program then indicated that an appropriate sample size for the peer review was 287 exams to be reviewed. T:24.[9]

After obtaining the sample size, Dr. Morrissey's next step was to obtain a reviewer. T:24. In choosing a reviewer, Dr. Morrissey sought a radiologist who could be trusted and was reliable, *i.e.*, a board-certified radiologist from a reputable school who could use a computer. T:24-25. Dr. Morrissey hired Dr. Benjamin Sacks to perform the peer review, who was paid $1,800 per day for a week-long period.[10] T:25, 73. Dr. Sacks performed the peer review at the RSI offices. T:25. Dr. Morrissey did not give Dr. Sacks instructions as to what studies to examine. T:51-52.

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[8] Dr. Morrissey determined that the universe was comprised of approximately 91,000 radiology images. T:15-16, 22. These images were organized by a series of spreadsheets, which were divided by month. T:27.

[9] Dr. Morrissey's numbers were more stringent than the minimum requirements identified by HHS. T:23-24. Had she used the minimum values recommended by the RAT-STATS program, the sample size would have been 49. *See* T:24.

[10] Dr. Sacks was later hired as a permanent RSI employee. T:52-53. At the time he performed the peer review, he did not know that there was a federal investigation of the defendant. T:79.

Before Dr. Sacks began the peer review, Dr. Morrissey went to RSI's IT manager, Dan Rabideau. T:26. Dr. Morrissey gave Rabideau the 91,000 files and "told him . . . that the cases need to be presented to Dr. Sacks in a random manner, and [she] need[ed] a way for those cases to be loaded onto his workstation." T:66, *see also* T:26, 49. The exams needed to be "extracted at a random basis," T:26, and the random generation of images "was the most critical point," T:27. This meant that every one of the 91,000 reports had an equal chance of being selected in the sample. T:48. Rabideau then created a computer program to generate a random sample. T:26. Because of the volume of cases, Rabideau could only create spreadsheets for the cases month-by-month. T:49-50, 67. The purpose was to try "to make it . . . as unbiased as possible and to make it very objective." T:50. Dr. Morrissey told Rabideau the months that she was looking at and to start from March 2008 and go backwards. T:28, 61. "There was no rhyme or reason for it, just pick one month and move." *Id.*

B. Dr. Benjamin Sachs

1. Qualifications

Dr. Sacks graduated from Cornell University with a B.A. in biology in 1998. T:70; Def't Exh. 5. He then obtained his medical degree from UCLA in 2003. T:71. Dr. Sacks did an internship and had a four-year residency in diagnostic radiology at

Emory University from July 2003-June 2008. T:71; Def't Exh. 5. He then became a board-certified radiologist in June 2008. T:71. While at Emory, Dr. Sacks did not personally perform peer reviews, but the attending doctors with whom he was working taught Dr. Sacks to use the RADPEER peer review process and Dr. Sacks observed the process in his training. T:74, 90. He did not have any additional training such as classes or seminars to prepare for the peer review process.[11] T:92-93. At the time of the peer review, Dr. Sacks had not worked in a radiology practice. T:93.

2. Methodology

Dr. Sacks performed a peer review for RSI in September 2008 using the RADPEER peer review process. T:72, 89. The RADPEER review was instituted by the American College of Radiology as their model for peer review. T:75. The review uses a four-point scoring system to grade the prior studies. T:76-77. A score of 1 indicates that the reviewing radiologist concurs with the prior reports. T:77, 78. A score of 2 indicates a minor discrepancy that is not expected to be identified while a 3 is a more obvious error that should be picked up most of the time. T:77. A score of 4

[11] Prior to the peer review for RSI, Dr. Sacks had never officially peer reviewed prior radiological images, but he had a "brief exchange" with an attending physician in Atlanta in which he asked for an opinion regarding the peer review process. T:91.

indicates a "gross miss," meaning that a significant finding was missed and was obvious enough that it would have been identified by a well-trained, competent radiologist. T:77. Thus, the peer review process requires a doctor to examine an earlier report by a doctor and state whether the doctor concurs or disagrees with the report. T:75, 110.

Dr. Sacks was told that RSI was starting a peer review process and needed a certain backlog of cases to be reviewed. T:95. Dr. Sacks was not part of the process in determining the number of studies he needed to review. T:105. To perform the peer review, Dr. Sacks was presented a spreadsheet with a list of 50 lines. T:80, 95. Dr. Sacks believed that the list of 50 was random. T:80. He left it to the IT staff to generate the lists. T:94. Each line would contain a patient name and the type of image or "modality" (X-ray, CAT scan, MRI, ultrasound). T:80; *see also* Gov't Exh. 4. Dr. Sacks would then select the study that he wanted to view, which would lead to the image being loaded onto the screen. T:79, 80. In selecting images, Dr. Sacks had discretion in choosing images, and he decided to review different types of images. T:81, 109. Dr. Sacks "felt that to do a valid peer review [he] needed to include representative studies from all the different" images. T:81. There was no set criteria for how many types of images that Dr. Sacks needed to review, and he chose a

representative sample based on "gestalt" or his gut feeling. T:105. Dr. Sacks would then review the selected image and the prior report, and he would state whether he concurred or disagreed with the report using the RADPEER scoring system. T:79-80, 111. He ultimately reviewed 1,060 images between March 2008 and October 2007, and he stopped at 1,060 images[12] because Dr. Morrissey informed him that they had collected enough samples. T:82, 87, 114; *see also* Gov't Brief at 10-11 in Doc. 83 (summarizing number of images reviewed by Dr. Sacks and the month that these images were reviewed).

Discussion

Following the evidentiary hearing, the government argues that Dr. Sacks's peer review testimony should be excluded under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). [*See generally* Doc. 83]. In *Daubert*, the Supreme Court expounded on the district court's role as a gatekeeper in determining whether expert

[12] For reach month, Dr. Sacks reviewed the following number of images: (1) 472 from March 2008, which comprised 45% of the 1,060 reviewed; (2) 251 from February 2008 (24%); (3) 101 images from January 2008 (10%); (4) 100 from December 2007 (9%); (5) 99 from November 2007 (9%); (6) 36 from October 2007 (3%); and (7) 0 from September 2007 to March 2007. [*See* Doc. 83 at 10-11].

testimony on scientific matters is admissible under FED. R. EVID. 702.[13] *Daubert*, 509 U.S. at 589. The Court stated that a district court "must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable," and that the court must screen out "expert" testimony that is not sufficiently reliable or trustworthy for the factfinder to consider. *Id.* at 589. This means that "[t]he trial court must 'make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.' " *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). To evaluate the admissibility of expert testimony, *Daubert* requires the district courts to"engage in [the following] rigorous three-part inquiry": (1) whether the expert is qualified to testify about the matters to be addressed;

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[13] Rule 702 states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED. R. EVID. 702.

(2) whether the methodology used in reaching the expert's conclusions is reliable; and (3) whether the testimony assists the trier of fact through application of the specialized expertise to understand the evidence or to determine a fact in issue. *United States v. Frazier*, 387 F.2d 1244, 1260 (11th Cir. 2004) (*en banc*); *Quiet-Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003). These are "distinct concepts" that must be evaluated separately. *Frazier*, 387 F.3d at 1260. Since the proponent bears the burden of proving admissibility, the proponent of the expert "bears the burden of showing, by a preponderance of the evidence, that the testimony satisfies each prong." *Hendrix ex rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183, 1194 (11th Cir. 2010); *see also Frazier*, 387 F.2d at 1260. The undersigned examines whether the defendant met his burden for each of the three *Daubert* factors.

A. Qualifications

The government argues that the defendant's experts are not qualified in the field of statistics or sampling. [Doc. 83 at 12-17]. As for Dr. Morrissey, the government asserts that her statistics course work and history of working with statisticians does not demonstrate that she is qualified in the area of designing and implementing a sampling methodology. [*Id.* at 13]. In the government's view, Dr. Morrissey has the following deficiencies: (1) she had never designed such a sampling methodology before; (2) she

had never previously worked with the RAT-STATS program; (3) she did not consult with anyone for guidance; and (4) her general knowledge of statistics does not qualify her as an expert. [*Id.* at 13-15]. As for Dr. Sacks, the government first notes that the defendant has not tried to demonstrate that he was qualified to offer opinions about statistics or sampling. [*Id.* at 16]. The government argues that the defendant cannot rely on FED. R. EVID. 703 to testify that his peer review constitutes a valid sample, which would in effect bootstrap complicated expert testimony to his own testimony about the peer review. [*Id.*]. The government is of the opinion that Dr. Sacks should remain silent on the matter of statistics because he has no personal knowledge as to how the sample was generated or how the sample represents the broader universe. [*Id.* at 17].

The defendant initially notes that courts generally should favor admissibility of evidence and that the standard for determining whether an expert is qualified is "quite 'liberal.' " [Doc. 87 at 10]. The defendant then argues that his witnesses are qualified. As for Dr. Morrissey, the defendant argues that she is "eminently qualified" based on her history as a doctor, a peer reviewer, and a student of statistics. [Doc. 87at 14-15]. Based on this experience, the defendant argues that Dr. Morrissey investigated the best and most efficient method of performing a peer review and used a sampling method created by the United States government. [*Id.* at 15]. The defendant then argues that

Dr. Morrissey did not need to consult with HHS before implementing the peer review study and that the defendant does not need "to play 'mother may I' when defending" himself against allegations of criminal conduct. [*Id.*]. The defendant argues that the government's citation to other aspects of the RAT-STATS program is a red herring because Dr. Morrissey was the only expert who testified at the hearing and she only was trying to determine the base number for a random sampling. [*Id.* at 15].

As for Dr. Sacks, the defendant notes that the government has conceded his qualifications, but has challenged him as a "mouthpiece" for Dr. Morrissey. [*Id.* at 16]. The defendant then states that "the Court should realize that Defendant will call Dr. Morrissey as a witness at trial,"[14] so Dr. Sacks can testify about the work he performed in the peer review developed by Dr. Morrissey. [*Id.* at 16-17].

An expert may be qualified in various ways. "Under Fed.R.Evid. 702, a witness may be qualified as an expert by virtue of his or her 'knowledge, skill, experience, training, or education.' " *Quiet Tech.*, 326 F.3d at 1342. Therefore, the expert's

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[14] The undersigned notes that at the *Daubert* hearing, the defendant stated that his plan was to only call Dr. Sacks as a witness because "experts are generally authorized to testify based upon information that is itself not in the record. And it was my plan, frankly, was [sic] to simply do that. So I'm not asking to qualify her as an expert[.]" T:137-38. It therefore appears that the defendant has changed his mind and plans on calling Dr. Morrissey as a witness.

scientific training or education may be sufficient to qualify an expert. *Frazier*, 387 F.3d at 1260. Also, the individual's experience in the field may be sufficient to qualify an individual as an expert. *Id.* at 1261; FED. R. EVID. 702 advisory committee notes (2000). To determine whether a witness is qualified, "the trial court [must] examine the credentials of the proposed expert in light of the subject matter of the proposed testimony." *Jack v. Glaxo Wellcome, Inc.*, 239 F. Supp. 2d 1308, 1314 (N.D. Ga. 2002) (Pannell, J.). This inquiry has been described as "a relatively low threshold." *R&R Int'l, Inc. v. Manzen, LLC*, No. 09-60545-CIV, 2010 WL 3605234, *7 (S.D. Fla. Sept. 12, 2010) (quoting *Furmanite Am., Inc. v. T.D. Williamson*, 506 F. Supp. 2d 1126, 1129 (M.D. Fla. 2007)).

The undersigned concludes that Dr. Morrissey and Dr. Sacks do not qualify as experts. As for Dr. Morrissey, the defendant sought to show that she designed a statistically valid peer review to evaluate the accuracy of the defendant's radiology reports. There is nothing in Dr. Morrissey's background that suggests she was qualified to design such a peer review. First, Dr. Morrissey has no degree in statistics or designing peer reviews. *See* Def't Exh. 4; T:30, 32. The undersigned recognizes that she has studied statistics and supervised statisticians, but she does not have a statistics degree or an educational background that suggests she could employ statistical

techniques to develop peer review procedures. Second, the defendant has not demonstrated that Dr. Morrissey has any special training or experience in developing peer review studies. Dr. Morrissey has not designed such a peer review in the past. *See* T:32. She had not used the RAT-STATS program in making statistical analyses prior to the peer review. T:38-39. Her past work as a peer reviewer did not involve developing peer review processes, but instead was to actually review the work of other doctors. T:30. While Dr. Morrissey's training in internal medicine and Harvard degree in public health are impressive, these experiences do not demonstrate that she had any particular knowledge or skill in designing peer review studies. Her exposure to statistics and performing peer reviews are insufficient to demonstrate her expertise in designing statistically valid peer review studies. *See United States v. Brown*, 415 F.3d 1257, 1269 (11th Cir. 2005) (concluding that expert was not qualified in chemistry because his professional experience focused on plant pathology and botany and he only worked with controlled substances on isolated projects and lacked a license to work in controlled substances); *cf. United States v. Paul*, 175 F.3d 906, 911 (11th Cir. 1998) (noting that witness qualified as an expert in handwriting analysis because of his 30-year experience as a handwriting analyst, his membership in handwriting analysis

organizations, teaching experience in handwriting analysis, and training of handwriting examiners).

Like Dr. Morrissey, the undersigned concludes that Dr. Sacks is not qualified to testify as to the statistical validity of the peer review. As summarized by the defendant, Dr. Sacks would testify "that after reviewing [a] random selection of 1060 cases in which an RPA performed an initial evaluation of a report signed by Dr. Reddy, 'there were no misrepresentations or patient issues identified.' " (*See* Def't Exh. 5). Thus, Dr. Sacks's testimony would need to cover two subjects: (1) that he randomly selected images to review; and (2) that review the images using the RADPEER procedure found no errors. The government does not dispute Dr. Sacks's qualifications as to the second task. [*See* Doc. 83 at 16 n.10]. As a result, the undersigned focuses on Dr. Sacks's qualifications for randomly selecting images and concludes that Dr. Sacks was not qualified to do so. The peer review procedure as designed by Dr. Morrissey was intended to be a random sampling. T:26 ("What I needed was a -- the exams to be extracted at a random basis."). Although Dr. Morrissey may not have intended to delegate the task of random selection to Dr. Sacks, *id.*, the task of randomly selecting images essentially became Dr. Sacks's task when he had to select images to review from the spreadsheets. T:80-81. His background, as he readily admitted at the hearing,

is not in statistics. T:105 ("I had no sense of statistics."). Dr. Sacks therefore is not qualified as an expert in statistics and cannot testify about how the sample selected represents the broader universe of radiology images or that the peer review has any statistical significance.

Accordingly, the undersigned concludes that the testimony of Dr. Sacks and Dr. Morrissey should be excluded under *Daubert* because they are not qualified experts in statistics or designing statistically significant peer review procedures. However, even if the doctors were qualified, the undersigned would conclude that they have not used reliable methodology as explained below.

B. Reliability of the Methodology

The government argues that the defendant has not shown that the methodology employed in generating the sample is reliable. [Doc. 83 at 17-22]. The government asserts that Dr. Sacks's peer review was not of a random sample because: (1) it skewed toward the months of February and March 2008; (2) the images were not selected randomly as Dr. Sacks had discretion in making choices; and (3) the method cannot be tested because the sample was chosen based on Dr. Sacks's gut feeling. [*Id.* at 20-21]. The government therefore argues that the peer review was flawed in its design and its application and is therefore unreliable. [*Id.* at 22].

The defendant responds that the methodology of the peer review was reliable. First, he argues that the peer review was not skewed to a period outside the indictment because there is no evidence that the defendant was aware of a federal criminal investigation in February or March 2008. [Doc. 87 at 17]. The defendant asserts that even excluding the studies reviewed by Dr. Sacks from February and March 2008, Dr. Sacks reviewed over 300 studies, which was well above the base line of 287 identified by Dr. Morrissey. [*Id.* at 17-18; *see also id.* at 19 ("If the government's RATSTATS program required merely 287 studies to perform a random analysis . . ., then the 300 studies reviewed by Dr. Sacks . . . in these four months far exceed the minimum needed for a valid review.")]. The defendant also notes that if the studies from February and March 2008 are excluded, then the universe of studies under consideration would be lower as would be the sample size. [*Id.* at 18]. The defendant further contends that Dr. Sacks's review focused on the months from the indictment. [*Id.* at 18]. Finally, the defendant complains that "[t]he problem . . . is that it is difficult to perform statistically valid review when the prosecution keeps changing the period under focus." [*Id.* at 19].[15]

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[15] The undersigned notes that this argument appears to ignore the evidence. The peer review designed by Dr. Morrissey was "not for presentation in court," T:53, and was performed in September 2008, T:52. The defendant was not indicted until

Second, the defendant argues that although Dr. Sacks consciously sought to obtain a cross section of the different types of images, Dr. Sacks's review was random because he selected studies from a randomly selected group of 50 images. [*Id.* at 19-20]. Third, the defendant characterizes as "specious" the government's argument concerning the replicability of the peer review because the government could hire its own board-certified radiologist to perform the peer review. [*Id.* at 21].

The government's reply brief focuses solely on whether Dr. Sacks's review constituted a random sampling and argues that the peer review was not random. [*See generally* Doc. 89]. The government notes that Dr. Morrissey explained "the most critical point" for the peer review was that the images be randomly selected from the total universe, which is confirmed by the Federal Register notice and the RAT-STATS manual. [*Id.* at 2-3]. The government then argues that Dr. Sacks's method of choosing studies was not performed randomly. First, the government asserts that the sample was skewed because it was not picked across the entire population as Dr. Sacks's review was weighted heavily toward March and February 2008 and the review did not evaluate any studies from the universe between March 2007 and September 2007. [*Id.* at 4-5].

November 3, 2009, over one year after the peer review. As a result, it is not clear why the defendant takes issue with the prosecution changing the period of focus in trying to argue the reliability of the peer review.

Second, the government argues that Dr. Sacks inserted subjectivity into the selection process by relying on his gut feeling for choosing studies to review. [*Id.* at 5-6]. The government discounts the defendant's argument that Dr. Sacks chose from lists of 50 randomly selected items because Dr. Sacks's use of his gut removed the random nature of the selection. [*Id.* at 6]. The government points out that the defendant did not show that such use of a gut feeling was acceptable methodology and that Dr. Morrissey did not attempt to assure that the sample was chosen correctly. [*Id.* at 6-8]. As for the fact that Dr. Sacks reviewed more images than the sample size required, the government asserts that this argument does not demonstrate that the images were properly selected. [*Id.* at 8].

As the proponent of Dr. Morrissey's and Dr. Sacks's opinions, the defendant bears the burden of proof as to the reliability of a proffered expert's opinions, and the admissibility must be shown by a preponderance of evidence. *Kilpatrick*, 613 F.3d at 1335. Although an individual is qualified as an expert, her testimony may still be unreliable. *Frazier*, 387 F.3d at 1261. The issue is not whether the field in general uses a reliable methodology, but the reliability of the expert's methodology in the case at bar. *Daubert*, 509 U.S. at 591. This Court must determine whether the expert's testimony rests on a reliable foundation by examining whether: (1) "the reasoning or

methodology underlying the testimony is scientifically valid" and (2) the reasoning or methodology can be applied to the facts in the case. *Frazier*, 387 F.3d at 1261-62 (quoting *Daubert*, 509 U.S. at 592-93). *Daubert* identified a list of "general observations" for determining whether expert testimony is sufficiently reliable to be admitted under Rule 702. *Daubert*, 509 U.S. at 593. Those general observations focus on four primary inquiries about the expert's theory or technique: (1) whether it can be (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) what its known or potential rate of error is, and whether standards controlling its operation exist; and (4) whether it is generally accepted in the field. *Id.* at 593-94.

The Supreme Court subsequently held that whether the *Daubert* factors are even pertinent to assessing reliability in a given case will "depend[ ] on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho Tire*, 526 U.S. at 153 (internal marks omitted). Because the applicability of the *Daubert* factors depends on the individual facts in a particular case, the Supreme Court stated that it could "neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert*, nor [could it] now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue." *Id.* at 150. As a result, courts

have relied on other factors in determining the reliability of an opinion including: (1) the sufficiency of the relationship between the expert's technique and the methods that were established reliable; (2) the expert's qualifications[16]; (3) the use of the method in non-judicial settings; (4) whether the proposed testimony grows naturally and directly out of the research that the expert conducted independent of litigation; (5) whether the expert unjustifiably extrapolated from an accepted premise to an unfounded conclusion; (6) the expert's consideration of alternative explanations; (7) whether the expert is being as careful as she would be in her professional work; and (8) whether the field of expertise is known to reach reliable results. *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594-95 (D.N.J. 2002); *see also* FED. R. EVID. 702, advisory committee notes (2000); John Hardin Young, *Young's Federal Rules of Evidence* Art. VII (7th ed.).

The undersigned concludes that the methodologies used by the doctors to create and implement the peer review was not reliable and accordingly that the results obtained from Dr. Sacks's peer review were not reliable. First, even if Dr. Morrissey

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[16] The Eleventh Circuit has noted that "there are instances in which a district court may determine the reliability prong under *Daubert* based primarily upon an expert's experience and general knowledge in the field." *Kilpatrick*, 613 F.3d at 1336 (citing *United States v. Brown*, 415 F.3d 1257 (11th Cir. 2005)).

and Dr. Sacks were qualified, their qualifications are minimal, which suggests that the methodologies in creating and implementing the peer review are unreliable. As explained above, Dr. Morrissey had no experience in designing a peer review procedure. Also, the defendant did not show that Dr. Morrissey's study of statistics prepared her to design a statistically valid peer review. Even if she had such expertise, her efforts were undermined by Dr. Sacks who was delegated the task of randomly selecting images to review. Dr. Sacks has no statistical knowledge to do so. His description of his selection process was based on belief and gestalt in that he chose images based on his gut and his belief that different types of images should be reviewed. T:81, 105. There is no indication that the selection was driven by any expertise or any scientific or specialized processes. The doctors' lack of expertise in statistics and peer review design indicates that the methodologies in trying to obtain a statistically valid peer review results were unreliable.

Second, beyond the qualifications problem, the reliability of the peer review results is undermined because the results were not random. Dr. Morrissey wanted the results to be obtained in a random manner, and believed that this "was the most critical point." *See* T:26-27. Dr. Morrissey testified as follows concerning the critical aspect of randomness:

> Q. And am I right that the idea behind random sampling is that you are to pick randomly among that entire universe for whether it's 287 or 49 or whatever the sample size is going to be, you are going to pick randomly among the entire universe to get to that sample; is that right?
>
> A. Right.
>
> Q. And by randomly that means that every member of the universe, so to speak, every one of the 90,000-or-so reports has an equal chance that's greater than the other of being selected to be in the sample; is that the idea?
>
> A. Right. Yes.
>
> Q. And, by the way, so the 90,000 just to make sure that we're clear, am I right that what that means is that there were 90,000 or so, I mean, give or take, approximately 90,000 radiology reports signed by the Defendant between April or May 2007 through March or April of 2008, so that 11-month-or-so – 11-or-12-month period 90,000 reports; is that correct?
>
> A. I believe so.

T:48. Although randomness was critical to the peer review, the review was not implemented to obtain a random sampling. Initially, the program employed by the IT department of RSI did not ensure that "every one of the 90,000-or-so reports ha[d] an equal chance" of being selected. Although it created a spreadsheets with 50 randomly selected images, the selection was performed by month. As a result, the program did not ensure that "every one of the 90,000-or-so reports ha[d] an equal chance" of being

selected because it randomly selected images on a monthly basis not on the basis of the entire universe.

Also, aside from the flaw in the IT department's program, the random nature of the selection process was ruined by giving Dr. Sacks discretion in choosing images. Dr. Sacks readily admitted that he had no statistical knowledge and that his selection was based on two factors - - the belief that he had to review all modalities and his gut feeling. Dr. Sacks's lack of statistical knowledge indicates that his decisions in selecting images would not result in randomness. The defendant further did not present any evidence that such selection processes result in random selections.

Finally, even if Dr. Sacks's gut feeling procedure resulted in random choices, the peer review did not ensure that "every one of the 90,000-or-so reports has an equal chance" of being selected because Dr. Morrissey halted Dr. Sacks's review in October 2007. T:87. This decision ensured that the entire universe of reports did not have an equal chance of being selected because Dr. Sacks was not provided the opportunity to select from the remaining universe of radiology images. In other words, his review could not be random because it did not consider the entire universe of images. [*See* Doc. 83 at 10-11 (demonstrating that the review stopped in October 2007 without a

review of any images from September 2007 - March 2007, which were part of the universe of images to be reviewed)].

The defendant seems to believe that because Dr. Sacks reviewed more than the 287 images required by RAD-STATS, his review somehow complies. This argument does not demonstrate that there was a random selection of images. Based on the undersigned's understanding of the evidence, there are at least two components needed for Dr. Sacks to testify that his peer review has any statistical significance: (1) the sample size is sufficiently large; and (2) the sample size was randomly chosen. This 287 figure only speaks to the first component - - the size of the sample. It says nothing about whether Dr. Sacks's review of 287 images was randomly performed. As explained above, the evidence indicates that Dr. Sacks's review was not random.

Third, there is no indication that the methodology can be tested. As the government identifies, an essential component of the peer review was Dr. Sacks's gut feeling. The defendant has not shown that this gut feeling can be tested to determine if the results of the peer review have statistical significance. The defendant suggests that the government can counter this evidence at trial by presenting its own expert, but this argument ignores the difficulty in testing a methodology that relies on another's gut feeling.

Fourth, the defendant has not demonstrated that the methods employed are those generally used in the fields of statistics or peer review design. There is no indication that the RAD-STATS program is used to obtain random samples for medical peer reviews. However, even if it were, the defendant did not develop any evidence to show that Dr. Sacks's approach to selection by gut feeling is used for obtaining a statistically significant peer review results.

Given these problems with the methodology employed in developing and implementing the peer review, the undersigned concludes that the defendant has not demonstrated by a preponderance of evidence that Dr. Morrissey's and Dr. Sacks's testimony is reliable for purposes of showing that the peer review is evidence of the accuracy of the defendant's reports. In the event that the District Court disagrees with these conclusions, the undersigned addresses whether the doctors' evidence is relevant.

C. Relevance

The government argues that there are two relevancy problems with Dr. Sacks's testimony. First, the government argues that Dr. Sacks's peer review primarily focused on a period that was outside of the indictment period and therefore will not demonstrate whether the defendant actually reviewed the radiology tests. [Doc. 83 at 23]. Second, the government argues that Dr. Sacks's peer review testimony only involved a small,

non-random percentage of the 91,000 images. [*Id.* at 23-24]. The government adds that any potential relevancy is far outweighed by the risk of prejudice, delay and confusion because the government would have to present evidence at trial highlighting the flaws in the methodology and the unrepresentative nature of the sample. [*Id.*]. Further, the government contends that Dr. Sacks's peer review testimony is really a side issue because the trial will not be about whether the defendant's reports were accurate but about whether he fraudulently passed off the reports as his own. [*Id.* at 24-25]. Finally, the government believes that injecting the issue of patient harm into the trial would turn the trial into a medical malpractice case since it would have to provide evidence rebutting the defendant's assertion of no harm. [*Id.* at 25].

The defendant argues that the undersigned should not consider relevancy and should leave this issue to the District Court who will hear the evidence and be in a better position to determine how the evidence fits within the framework of the trial. [*Id.* at 21]. The defendant contends that even if the government's relevancy arguments are considered, they must fail. [*Id.* at 21-23]. First, the defendant notes that Dr. Sacks's review of over 300 studies for the relevant period are above the 287 needed for a proper sample size and are part of the period on which the government's indictment focuses. [*Id.* at 22]. Second, the defendant asserts that the government's

needle in the haystack argument shows its misunderstanding of random sampling and does not detract from the relevancy of Dr. Sack's peer review. [*Id.* at 22-23]. Third, the defendant argues that the government's prejudice argument ignores the realities of trial in which both parties present evidence, so requiring the government to present evidence of the methodology's flaws is appropriate. [*Id.* at 23]. Fourth, the defendant asserts that patient harm is an issue given the allegations that he did not review radiology images, so the lack of patient harm "shows much." [*Id.* at 24]. Additionally, the defendant asserts that "[a] random sampling and a review by another board-certified radiologist is valuable evidence for the jury when it evaluates the government's various witnesses." [*Id.* at 23-24]. Finally, the defendant argues that if the admission of Dr. Sacks's testimony requires the government to present rebuttal evidence, this will allow the defendant to show that his work withstands scrutiny. [*Id.* at 24].

The third part of the *Daubert* inquiry - - whether an expert's testimony assists the trier of fact - - primarily relates to relevance. *Daubert*, 509 U.S. at 591; *Phillips v. Am. Honda Motor Co., Inc.*, 238 Fed. Appx. 537, 540 n.2 (11th Cir. July 3, 2007) ("[W]hen an expert's data is not directly relevant to the matter at issue in a case, the expert's testimony does not assist the trier of fact and is therefore inadmissible under *Daubert*."). As a result, the undersigned rejects the defendant's contention that the

undersigned should leave this issue for the District Court to resolve because relevance is part of the *Daubert* inquiry. *McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004) ("[T]he Daubert analysis requires that the proposed testimony be relevant."). Although Defendant stated that a relevance determination should be left to the District Court and he was not arguing relevance at the evidentiary hearing (*see* discussion at T:127-137), relevancy is part and parcel of the *Daubert* inquiry, and any additional hearing is not necessary to determine relevancy. Therefore, the undersigned examines whether the expert evidence is relevant.

An expert's testimony is relevant if " 'it logically advances a material aspect' of the case." *McDowell*, 392 F.3d at 1299 (quoting *Daubert*, 509 U.S. at 591). The testimony must assist the trier of fact by relating to an issue in the case. *Daubert*, 509 U.S. at 591. This testimony must also "fit" the facts in issue, *i.e.*, it must be tied to the facts of the case so as to aid the jury in resolving a factual dispute. *Daubert*, 509 U.S. at 591; *see also Quiet Technology*, 326 F.3d at 1347 (noting that *Daubert* identified two aspects of relevance - - fit and relating to an issue in the case).

Even if an expert's testimony is otherwise admissible and helpful to a jury, a trial court may exclude the testimony under Rule 403 of the Federal Rules of Civil Procedure. *Frazier*, 387 F.3d at 1263. Rule 403 provides:

> Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

FED. R. CIV. P. 403. Therefore, an expert's opinion may be excluded under Rule 403 if: (1) the testimony's probative value is outweighed by its potential to confuse or mislead the jury; and (2) the testimony is cumulative or needlessly time consuming. *Frazier*, 387 F.3d at 1263. The Eleventh Circuit has instructed that because a jury might give "talismanic significance" to expert testimony, the district court must be careful in weighing the probative value of the evidence against its potential to confuse or mislead. *Id.*

The basic premise of the second superseding indictment is that between May 2007 and January 2008, the defendant falsely represented that he reviewed radiology images and drafted radiology reports by signing reports without reviewing the images or editing the draft reports in contravention of a radiologist's standard of care. [*See* Doc. 67 ¶¶ 3, 3B-3C]. The defendant's defense is that he reviewed the images and reports, and he seeks to use Dr. Sacks's peer review testimony as evidence that he reviewed images and reports. The defendant's theory is that the peer review showed

in a statistically significant manner that the reports are accurate and in turn that the accuracy of the reports is evidence that he reviewed these images and reports.

The undersigned is persuaded by the government's argument that the peer review is not relevant to the facts in this case.[17] The indictment relates to a period between May 2007 through January 2008. Dr. Sacks's peer review focused on radiology images and reports from March and February 2008, representing 69% of the images evaluated for the peer review. Those images that were reviewed from the period identified in the indictment constitute only 31% of the peer review. Given the peer review's heavy

[17] Although the undersigned agrees with the government that the peer review is not relevant, this finding does not mean that the undersigned agrees with every relevancy argument presented by the government. First, to reach the relevance argument, the undersigned must assume the doctors were qualified and that there methodology was sound. Given these assumptions, the undersigned does not find it prejudicial to require the government to present evidence at trial demonstrating the flaws in the methodology. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). Second, the undersigned does not interpret the defendant's attempt to use the peer review evidence as a side issue because the defendant's defense is that he reviewed each image, which he would attempt to show in part by noting that his reports are accurate as demonstrated by the peer review. Finally, the peer review evidence should not inject the issue of patient harm into the trial. The central issue is whether the defendant reviewed images and reports, so patient harm is irrelevant (contrary to the defendant's assertion). However, the peer review speaks to the accuracy of the reports, which may suggest that the defendant reviewed them. As such, the undersigned does not find that the peer review evidence would be irrelevant merely because it might implicate patient harm.

emphasis on images from March and February 2008, the undersigned finds that the peer review does not fit the facts of this case, which encompass May 2007 through January 2008.

The defendant asserts that the peer review still is relevant to the facts of the case because Dr. Sacks reviewed over 300 reports from the relevant period alleged in the indictment, which exceeded the required sample size of 287. There are two problems with this argument. First, as explained above, that Dr. Sacks reviewed a sampling of images greater than what RAT-STATS required fails to demonstrate that the review was random. Dr. Sacks's review is helpful only if it is statistically valid, which required a random review of images. *See* T:26-27. Second, the defendant did not identify any evidence that the peer review became valid and statistically significant merely because Dr. Sacks reviewed a number of images above the sample size required by RAT-STATS. According to Dr. Morrissey, the important element to the review was randomness, and there has been no showing that Dr. Sacks's review of images between January 2008 and October 2007 constitutes a review of a random sample size.[18] Without such evidence, the undersigned concludes that the peer review's focus on a

[18] Based on Dr. Morrissey's definition of randomness, Dr. Sacks's review of images from January 2008 to October 2007 would not be random because it did not encompass the entire universe under consideration. *See* T:48.

period outside of the indictment period does not fit the facts of the case and is therefore irrelevant.

Accordingly, the undersigned concludes that the evidence concerning the peer review and therefore the testimony of Dr. Sacks and Dr. Morrissey should be excluded from trial under *Daubert*.

Conclusion

For all the foregoing reasons, the undersigned **RECOMMENDS** that the government's motion to exclude expert testimony from trial, [Doc. 71], be **GRANTED**. The undersigned has now ruled upon all pretrial motions, and has not been advised of any problems preventing the scheduling of trial. Therefore, this case is **CERTIFIED READY FOR TRIAL**.

IT IS SO CERTIFIED AND RECOMMENDED, this 24th day of February, 2011.

ALAN J. BAVERMAN
UNITED STATES MAGISTRATE JUDGE